All 55 FDA Medicine Approvals in 2023.#JJ

1. **Wainua**

Active ingredient: eplontersen

Indication: to treat polyneuropathy of hereditary transthyretin-mediated amyloidosis

2. Filsuvez

Active ingredient: birch triterpenes

Indication: to treat polyneuropathy of hereditary transthyretin-mediated amyloidosis bullosa.

3. Fabhalta

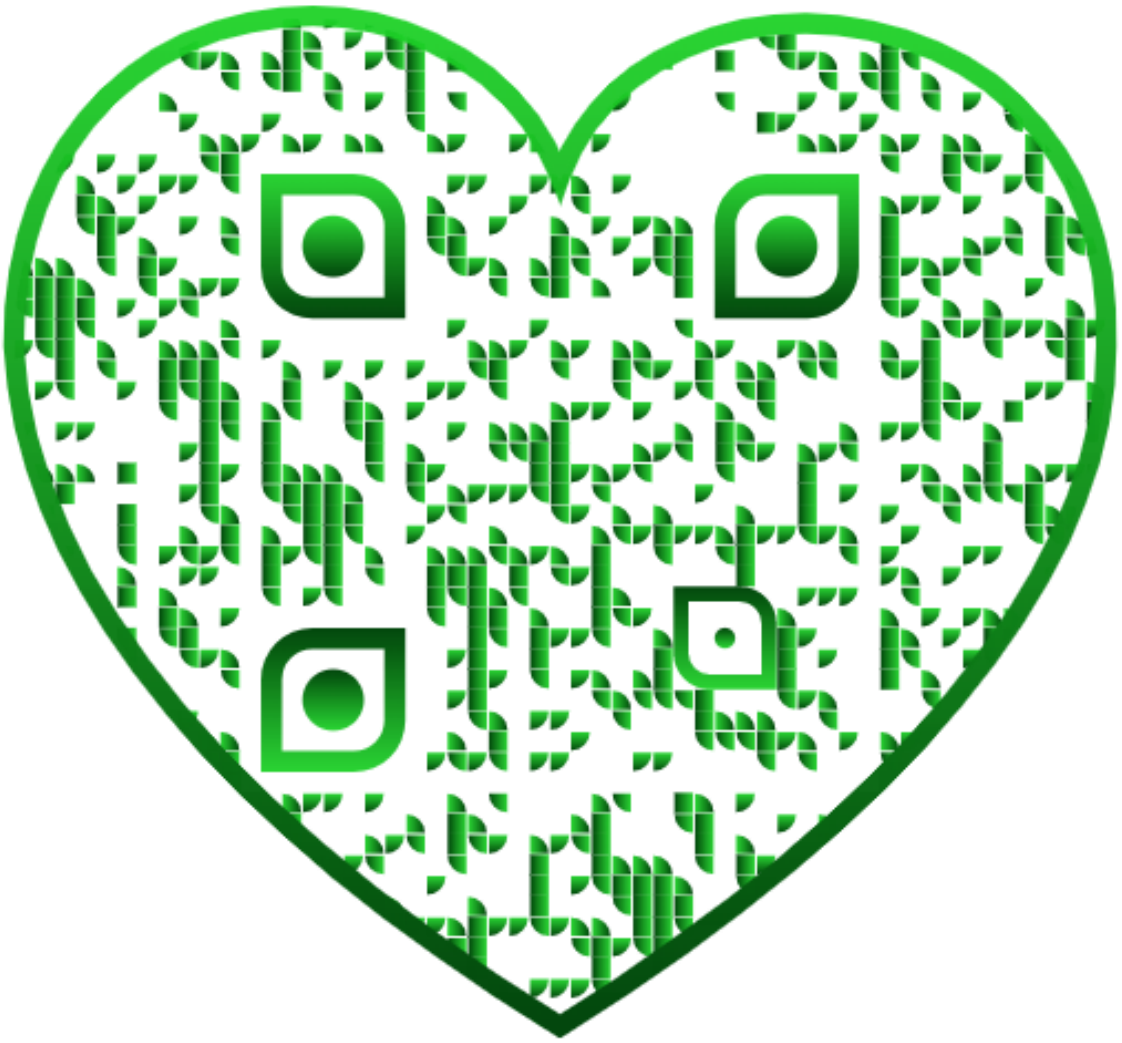
Active ingredient: iptacopan

Indication: to treat paroxysmal nocturnal hemoglobinuria.

4. Ogsivea

Active ingredient: nirogacestat

Indication: to treat adults with progressing desmoid tumors who require systemic treatment.



5. Truqap

Active ingredient: capivasertib

Indication: to treat breast cancer that meets certain disease criteria.

6. **Ryzneuta**

Active ingredient: efbemalenograstim alfa-vuxw

Indication: to treat neutropenia

7. **Augtyro**

Active ingredient: repotrectinib

Indication: to treat ROS1-positive non-small cell lung cancer.

8***. Defencath***

Active ingredients: taurolidine, heparin

Indication: to reduce the incidence of catheter-related bloodstream infections in adults with kidney failure receiving chronic hemodialysis through a central venous catheter.

9. **Fruzaqla**

Active ingredient: fruquintinib

Indication: to treat refractory, metastatic colorectal cancer.

10. **Loqtorzi**

Active ingredient: toripalimab-tpzi

Indication: To treat recurrent or metastatic nasopharyngeal carcinoma when used together with or following other therapies.

11. **Omvoh**

Active ingredient: mirikizumab-mrkz

Indication: to treat ulcerative colitis.

12. **Agamree**

Active ingredient: vamorolone

Indication: to treat Duchenne muscular dystrophy.

13. **Bimzelx**

Active ingredient: bimekizumab

Indication: to treat moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

14. **Zilbrysq**

Active ingredient: zilucoplan

Indication: to treat generalized myasthenia gravis in adults who are anti-acetylcholine receptor (AChR) antibody positive.

15. **Velsipity**

Active ingredient: etrasimod

Indication: to treat moderately to severely active ulcerative colitis in adults.

16. **Rivfloza**

Active ingredient: nedosiran

Indication: to lower urinary oxalate levels in patients 9 years and older with primary hyperoxaluria type 1 and relatively preserved kidney function.

17. **Pombiliti**

Active ingredient: cipaglucosidase alfa-atga

Indication: to treat late-onset Pompe disease.

18. **Exxua**

Active ingredient: gepirone

Indication: to treat major depressive disorder.

19. **Ojjaara**

Active ingredient: momelotinib

Indication: to treat intermediate or high-risk myelofibrosis in adults with anemia.

20. **Aphexda**

Active ingredient: motixafortide

Indication: to use with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma.

21**. Veopoz**

Active ingredient: pozelimab-bbfg

Indication: to treat patients 1 year old and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease.

22. **Sohonos**

Active ingredient: palovarotene

Indication: to reduce the volume of new heterotopic ossification in adults and pediatric patients (aged 8 years and older for females and 10 years and older for males) with fibrodysplasia ossificans progressiva.

23.**Elrexfio**

Active ingredient: elranatamab-bcmm

Indication: to treat adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy.

24. **Talvey**

Active ingredient: talquetamab-tgvs

Indication: to treat adults with relapsed or refractory multiple myeloma who have received at least four prior therapies.

25. **Izervay**

Active ingredient: avacincaptad pegol

Indication: to treat geographic atrophy secondary to age-related macular degeneration.

26. **Zurzuvae**

Active ingredient: zuranolone

Indication: to treat postpartum depression.

27. **Xdemvy**

Active ingredient: lotilaner

Indication: to treat demodex blepharitis.

28.**Vanflyta**

Active ingredient: quizartinib

Indication: to use as part of a treatment regimen for newly diagnosed acute myeloid leukemia that meets certain criteria.

29.**Beyfortus**

Active ingredient: nirsevimab-alip

Indication: to prevent respiratory syncytial virus (RSV) lower respiratory tract disease.

30.**Ngenla**

Active ingredient: somatrogon-ghla

Indication: to treat growth failure due to inadequate secretion of endogenous growth hormone.

31.**Rystiggo**

Active ingredient: rozanolixizumab-noli

Indication: to treat generalized myasthenia gravis in adults who are anti-acetylcholine receptor- or anti-muscle-specific tyrosine kinase antibody-positive.

32.**Litfulo**

Active ingredient: ritlecitinib

Indication: to treat severely patchy hair loss.

33.**Columvi**

Active ingredient: glofitamab-gxbm

Indication: to treat diffuse large B-cell lymphoma, not otherwise specified, or large B-cell lymphoma arising from follicular lymphoma after two or more lines of systemic therapy.

34. **Inpefa**

Active ingredient: sotagliflozin

Indication: to treat heart failure.

35. **Posluma**

Active ingredient: flotufolastat F 18

Indication: to use with positron emission tomography imaging in certain patients with prostate cancer.

36.**Paxlovid**

Active ingredients: nirmatrelvir, ritonavir

Indication: to treat mild-to-moderate COVID-19 in adults at high risk for progression to severe COVID-19.

37.**Xacduro**

Active ingredients: sulbactam, durlobactam

Indication: to treat hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex.

38.**Epkinly**

Active ingredient: epcoritamab-bysp

Indication: to treat relapsed or refractory diffuse large B-cell lymphoma (not otherwise specified) and high-grade B-cell lymphoma after two or more lines of systemic therapy.

39. **Miebo**

Active ingredient: perfluorhexyloctane

Indication: to treat signs and symptoms of dry eye disease.

40. **Veozah**

Active ingredient: fezolinetant

Indication: to treat moderate to severe hot flashes caused by menopause.

41. **Elfabrio**

Active ingredient: pegunigalsidase alfa-iwxj

Indication: to treat confirmed Fabry disease.

42. **Qalsody**

Active ingredient: tofersen

Indication: to treat amyotrophic lateral sclerosis in adults who have a SOD1 gene mutation.

43. **Joenja**

Active ingredient: leniolisib

Indication: to treat activated phosphoinositide 3-kinase delta syndrome.

44. **Rezzayo**

Active ingredient: rezafungin

Indication: to treat candidemia and invasive candidiasis.

45. **Zynyz**

Active ingredient: retifanlimab-dlwr

Indication: to treat metastatic or recurrent locally advanced Merkel cell carcinoma.

46. **Daybue**

Active ingredient: trofinetide

Indication: to treat Rett syndrome.

47. **Zavzpret**

Active ingredient: zavegepant

Indication: to treat migraine.

48. **Skyclarys**

Active ingredient: omaveloxolone

Indication: to treat Friedrich's ataxia.

49. **Filspari**

Active ingredient: sparsentan

Indication: to reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progression.

50. **Lamzede**

Active ingredient: velmanase alfa-tycv

Indication: to treat non-central nervous system manifestations of alpha-mannosidosis.

51. **Jesduvroq**

Active ingredient: daprodustat

Indication: to treat anemia caused by chronic kidney disease for adults on dialysis for at least four months

52. **Orserdu**

Active ingredient: elacestrant

Indication: to treat estrogen receptor-positive, human epidermal growth factor receptor 2-negative, ESR1-mutated, advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

53. **Jaypirca**

Active ingredient: pirtobrutinib

Indication: to treat relapsed or refractory mantle cell lymphoma in adults who have had at least two lines of systemic therapy, including a BTK inhibitor.

54. **Brenzavvy**

Active ingredient: bexagliflozin

Indication: to improve glycemic control in adults with type 2 diabetes mellitus as an adjunct to diet and exercise.

55. **Leqembi**

Active ingredient: lecanemab-irmb

Indication: to treat Alzheimer's disease.